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(71) Applicant (*for all designated States except US*): SATI-ETY, INC. [US/US]; 2470 Embarcadero Way, Palo Alto, CA 94303-3313 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): GANNOE, Jamy [US/US]; 935 Sherman Avenue, Menlo Park, CA 94025 (US). WELLER, Gary [US/US]; 15570 El Gato Lane, Los Gatos, CA 95032 (US). SUTTON, Douglas S. [US/US]; 1595 Adobe Drive, Pacifica, CA 94044 (US). GERBI, Craig [US/US]; 515 Villa Street, Mountain View, CA 94041 (US).

(74) Agent: NAGY, John, S.; Fulwider . Patton, Howard Hughes Center, 6060 Center Drive, Tenth Floor, Los Angeles, CA 90045 (US).

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(54) Title: METHOD AND DEVICES FOR MODIFYING THE FUNCTION OF A BODY ORGAN

(57) Abstract: Methods and devices for partitioning or plicating a region of a hollow body organ are described herein. These methods and devices relate generally to medical apparatus and methods and more particularly to devices and methods for affecting a change in the function of a hollow body organ, particularly a stomach, intestine or gastrointestinal tract. These changes can include reducing the volume capacity of the hollow body organ, disrupting or altering the normal function of the organ, functionally excluding certain sections of the organ either by affixing adjacent tissue or excising certain regions, or affecting or correcting the response of the organ to naturally occurring stimuli, such as ingestion.

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## METHOD AND DEVICES FOR MODIFYING THE FUNCTION OF A BODY ORGAN

### FIELD OF THE INVENTION

[0001] The present invention relates generally to medical apparatus and methods and more particularly to devices and methods for affecting a change in the function of a hollow body organ. These changes can include, for example, reducing the volume capacity of the hollow body organ, disrupting or altering the normal function of the organ, functionally excluding certain sections of the organ either by affixing adjacent tissue or excising certain regions, or affecting or correcting the response of the organ to naturally occurring stimuli, such as ingestion.

[0002] Reducing the volume of a hollow body organ by partitioning or plicating the organ, such as the stomach, results in a smaller reservoir within the organ that can hold only a reduced amount of food and thereby induce weight loss. In addition, such partitioning or plicating of the stomach may also prove efficacious for weight loss by affecting or interfering with stomach motility and/or decreasing gastric emptying time by reducing the organ's pumping efficiency in a variety of ways. For instance, excluding the fundus of the stomach may thereby decrease the pressure waves it generates and/or interfere with the muscular region of stomach (antrum) to slow pumping. In this way, the devices and methods disclosed herein can effect or correct the response of the organ to naturally occurring stimuli. A further effect of partitioning or plicating tissue in the stomach may relate to the treatment of gastro esophageal reflux disease or "GERD" by pinning the walls of the stomach together and thereby altering stomach distension and the

related "unrolling" of the lower esophageal sphincter (LES). Yet another effect of a single plication or series of plications may include causing scarring and stiffening of the region to similarly resist unrolling. Additionally, the methods and devices disclosed herein can exclude regions of the stomach organ, such as the fundus, to reduce capacitance, or to eliminate excretion of certain substances such as Ghrelin, the hormone closely associated with increased food intake.

[0003] The devices and methods disclosed herein may be used alone or in conjunction with each other. Furthermore, the devices may be permanently implanted or removed once they have served their purpose, e.g., the desired tissue effect has occurred (healing), or the clinical benefit has been achieved; for example, the patient has lost the directed or desired amount of weight, or the patient is no longer experiencing reflux.

#### BACKGROUND OF THE INVENTION

[0004] The current methods of treatment for gastrointestinal disorders, such as GERD, include medical intervention (drug therapy) or stimulation of lower esophageal region with RF or other energy. While effective to a certain degree, a more robust intervention would be desirable to achieve a longer term and more effective result.

[0005] In the case of severe obesity, patients may currently undergo several types of surgery either to tie off or staple portions of the large or small intestine or stomach, and/or to bypass portions of the same, e.g., to reduce the amount of food desired by the patient, and/or to reduce the amount of food absorbed by the gastrointestinal tract. Typically, these stomach reduction procedures are performed surgically through an open incision and staples or sutures are applied externally to the stomach or hollow body organ; however, several limitations exist due to the invasiveness of the procedures,

including, e.g., time, use of general anesthesia, healing of the incisions, and other complications attendant to major surgery.

[0006] There is a need for improved devices and procedures in treating both gastrointestinal disorders and severe obesity. In addition, because of the invasiveness of many of the conventional surgical procedures used to manipulate, in particular, the stomach, there remains a need for improved devices and methods for more effective, less invasive intragastric restriction or partitioning procedures.

#### **SUMMARY OF THE INVENTION**

[0007] The methods and devices employed to achieve the results disclosed herein are further set forth in United States Patent Application Serial No. 09/871,297 filed May 30, 2001, and United States Patent Application Serial No. 10/188,547 filed July 2, 2002, both fully incorporated herein by reference in their entirety. Accordingly, placement of intragastric partitions by the use of such devices and methods can be employed from within the gastric cavity to result in varying tissue geometries depending on the desired effect. The terms "plication", "partition", "fastening line", and "barrier" shall all refer to a zone where tissue folds or layers from adjacent or opposing regions of a hollow organ have been acquired and fixed so as to heal into a fused zone.

[0008] In one aspect, a variety of organ partitions or plications may be placed within the organ cavity to serve as barriers or "pouches" that are substantially separated from the majority of the organ cavity. For example, in the case where the stomach is partitioned, the "pouch" walls or partitions may be created just below the esophagus to reduce the volume of the stomach. This procedure has the effect of not only reducing the

volume of food that can be consumed by the patient, but also blocks, in the similar way a valve or splash might, the volume of any refluxant material that can contribute to GERD.

[0009] In another aspect, multiple partition lines or plications can be created and positioned to impact the motility of the organ in addition to reducing the effective volume of the body organ in which they are placed. In the case of a stomach, a reduction in motility has been shown to affect satiety and also the rate of gastric emptying, which in turn leads to less food intake and subsequent weight loss. (Villar, et al. *Mechanisms of satiety and gastric emptying after gastric portioning and bypass*, Surgery, August 1981 229-236.) The stomach may essentially be divided into two regions on the basis of its motility pattern. The upper stomach, including the fundus and upper stomach body, exhibits low frequency, sustained contractions that are responsible for generating a pressure within the stomach. The lower stomach, composed of the lower body and antrum, develops strong peristaltic waves of contraction. These powerful contractions constitute a very effective gastric pump. Gastric distention increases fundic activity and thus stimulates this type of contraction, thereby accelerating gastric emptying.

[0010] Disrupting this motility pattern can subdue or otherwise attenuate contraction waves initiated by the fundus of the stomach in response to distension. Such contractions in a non-partitioned stomach would transmit to the antrum of the stomach and facilitate gastric digestion and drainage. (Davenport *Physiology of the digestive tract*, 3<sup>rd</sup> Ed. 1971, Yearbook Medical Publishers, Chicago.) However, in a partitioned stomach, the contractions are decreased and/or the food passage pathways are attenuated by plications or fixation lines. As a further result, communication with the antrum and other stomach regions is less efficient as is the communication between the antrum and the

small intestine, thereby leading to a reduced rate of emptying. Furthermore, smaller pouches or multiple partitions within the stomach may also increase the pressure experienced by the fundus (fundic pressure) thereby enhancing the feeling of satiety with a lower volume of food.

[0011] In another aspect, it may be desirable to place a partition or plication to exclude the fundic region of the stomach organ from the other functioning regions to minimize the overall volume of the organ so as to limit food intake. Additionally, the plication or plications may be placed at the region of the stomach responsible for the secretion of certain "hunger hormones" to impair secretion and thereby control the impact of these hormones on hunger. Ghrelin, for instance, is a hormone produced primarily by the stomach (more concentrated in the fundic region) that has been shown to increase food intake. A marked suppression of Ghrelin levels has been correlated to the exclusion of large portions of the stomach following gastric bypass, thus contributing to the long term weight loss of a patient from such a procedure. (Cummings et al., *Plasma Ghrelin Levels after Diet-Induced Weight Loss of Gastric Bypass Surgery*, NEJM, Vol 346: 1623-1630, May 23, 2002.)

[0012] In yet another aspect, a partition line or plication may be placed substantially parallel to the lesser curve (LC) of the stomach organ, preferably just below the lower esophageal sphincter (LES) between the lesser curve (LC) and the greater curve (GC). Such a plication can function to reinforce the LES and therefore prevent its elongation or "unrolling" when the stomach organ distends in response to food or liquid intake.

[0013] When a patient experiences GERD, it may be associated with the LES being rendered incompetent. When the LES becomes incompetent, it fails to perform its valving or barrier function against the flow of gastric juices back into the esophagus from the higher pressure environment of the stomach. It has been documented that the overall length of the LES is critically important to its function as such a barrier. (DeMeester, *Evolving Concepts of Reflux: The ups and downs of the LES*, Can. J. Gastroenterol 2002; 16(5): 327-331.) Typically, the LES shortens as a natural response to gastric distension, such as when food is ingested into the stomach. If the LES is compromised or weakened, such distension can lead to the LES shortening or "unrolling" to the extent that it can no longer overcome pressure against it from the gastric cavity. This may result in refluxant from the gastric cavity entering the esophageal reservoir. Acutely, such contact can cause severe discomfort and other symptoms, and over time, can lead to serious complications such as cancer, ulcerations, esophagitis, Barrett's Esophagus etc.

[0014] A plication placed just below the LES within the gastric cavity, as referenced above, works to prevent the shortening or unrolling of the LES by stabilizing the region. The anterior and posterior walls of the gastric cavity may be fixed together to minimize the distension of the region in response to gastric filling. It is also possible to plicate adjacent walls such as the anterior wall of the stomach or posterior wall of the stomach to the LC or GC, walls from the GC to walls from the GC, or other combinations thereof. Such a plication can be placed substantially parallel with the LC of the stomach so as not to affect the volume of food intake for a patient. Alternatively, the plication can also be placed more horizontally if both stabilization and volume reduction of the region are desired. Certain tools have been employed to create an artificial sphincter such as

those described in United States Patents 6,475,136, and 6,254,642. Additionally, several devices have been suggested to plicate various regions of an organ, such as those described in United States Patents 5,403,326; 5,355,897; 5,676,674; 5,571,116; 6,447,533; 6,086,600; and Publications WO 02/24080; WO 01/85034; US 2002/0078967; and US 2002/0072761.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIG. 1 depicts various anatomical locations with respect to the gastrointestinal tract.

[0016] FIG. 2 depicts a schematic drawing showing a body organ with a partition or plication line placed to lessen the active reservoir of the gastric cavity.

[0017] FIGS. 3, 5 and 6 depict schematic drawings showing a body organ with partitions or plications placed to reduce the volume capacity and to interfere with the constant fundic pressure urging food into the antral pump.

[0018] FIG. 4 depicts a schematic drawing showing a body organ with partitions or plications placed to disrupt the motility function of the organ.

[0019] FIG. 7 depicts a schematic drawing showing distension of the gastric cavity and the resulting shortening of the LES.

[0020] FIG. 8 depicts a schematic drawing showing a plication or partition placed near the LES to control the impact of distension of the gastric cavity on the LES.

[0021] FIGS. 9 to 9B depict schematic drawings and cross-sectional views showing a plication of adjacent tissue placed along the length of the greater curve GCof

the stomach to exclude the plicated portion from contact with the remaining tissue in the organ (for example to impair secretion of the hormone Ghrelin).

#### DETAILED DESCRIPTION OF THE INVENTION

[0022] The present invention provides, in part, for methods and devices to manipulate, partition, divide or restrict a hollow organ and, more particularly, provides methods and devices to treat diseases, such as obesity and gastroesophageal reflux disease (GERD), that can be mediated by the gastrointestinal organs.

[0023] Figure 1 depicts an external view of various anatomical locations related to the gastrointestinal tract, including the esophagus (ES), lower esophageal sphincter (LES), gastroesophageal junction (GEJ), lesser curve (LS) of the stomach, greater curve (GC) of the stomach, fundic region of the stomach or fundus (FN), antrum of the stomach (AN), and pylorus (PY).

[0024] Figure 2 depicts an external view of a stomach organ 100 with an example of a partition or fastening line 101 placed in a location between the GEJ and the LC of the stomach 100. The partition 101 may be angled toward the LC relative to the GEJ to create a "pouch" (P) to achieve an overall reduction in volume of the active reservoir, i.e., the portion of the stomach 100 which is actively involved in food digestion. Arrows 102 represent the flow paths of potential refluxant that are prevented by the plication 101 from flowing upwards into the ES. In addition, pouch (P) operates to limit the volume of food or intake possible from the esophageal region (ES), and may therefore also effect weight loss in the target patient.

[0025] Figures 3 and 4 represent alternative placements of the partition or fastening line 101 to achieve various configurations of organ division. Each configuration may have a potential clinical application depending on the preference of the physician and clinical needs of the patient. In Figure 3, plications may be placed within the fundic region FN and may function to both lessen distension of that region in response to food intake. The plications may also inhibit the fundic reservoir's ability to produce contractions by either attenuating or baffling the frequency and/or intensity of the contractions to slow digestion and reduce gastric emptying time. Figure 4 shows yet another configuration of plications 101 located within the antrum AN region of the stomach 100. This placement is designed to disrupt or slow the contractile function of this region to slow gastric emptying time by interfering with the gastric pumping action and thereby enhance weight loss. As shown, the plications 101 may be aligned such that they point or extend angularly from the ES between the fundic region FN and a distal portion of the stomach 100. Plications 101 may extend partially within the stomach 100 or they may extend along a majority of a length of the stomach 100. Moreover, although only three plications 101 are shown, this is intended to be merely illustrative and a fewer or a greater number of plications may be utilized, depending upon the desired clinical results.

[0026] Figures 5 and 6 represent further alternative placements of partitions or fastening lines 101 within the stomach 100. The plications depicted in Figure 5 and 6 not only reduce organ volume, but also operate to effect organ motility, distension and pressure. The plications 101 shown in Figure 5 may be created such that they extend a partial length within the stomach 101 in a "radial" pattern extending between the LC and the GC. The plications 101 shown in Figure 6 may include a first plication 101 extending

from the GEJ and extending a length towards the AN with a second plication extending partially between the LC and the GC from a distal end of the first plication.

[0027] In Figure 7, stomach 100 is shown by the solid line 201 prior to intake of substances such as food or liquid. Measurement D1 represents the desired length of a healthy LES prior to food intake (in most cases, approximately 2 cm). Dotted line 202 depicts distension of the stomach following intake. Measurement D2 indicates shortening of the LES in response to the stomach 100 becoming distended. Once the LES shortens (e.g. in some cases to some length less than 2 cm), refluxant can then contact the esophageal region ES, as depicted by the arrows 204 which indicate refluxant flow paths, as the pressure created within the stomach 100 overwhelms the closing pressure of the shortened sphincter region D2. Figure 8 depicts a stomach undergoing similar distension to that as shown in Figure 7; however, plication 301 has been created at the base of the LES extending from the LES into the stomach. This placement of the plication 301 may limit the ability of the LES to shorten in response to gastric cavity distension. As a result, upon distension, D1 may approximately equal D2 after stomach distension where D2 may be greater than or equal to 2 cm. This measurement is approximately the length of a healthy functional LES, post stomach distension. Plication 301 is shown as extending partially into the stomach cavity; yet plication 301 may alternatively extend along a majority of the stomach cavity as well. The angle at which plication 301 extends relative to a longitudinal axis of the LES may also vary. For instance, plication 301 may be parallel to the longitudinal axis, or they may be relatively angled over a range suitable for preventing the LES from unrolling.

[0028] Figure 9 depicts a schematic of a procedure where adjacent tissue (e.g., tissue from along the greater curve GC of the stomach) is acquired and plicated in a pattern configured to exclude certain portions of the stomach organ (e.g., fundus). Excluding certain portions, such as the fundus, from the other functioning regions of the stomach not only minimizes the overall volume of the organ so as to limit food intake, but also impairs the secretion of certain hormones, e.g., Ghrelin, which helps to control hunger levels. Suppression of Ghrelin or the exclusion of Ghrelin from the remaining stomach may suppress a hunger response in a person to facilitate weight loss. Plication line 402 can start at the GEJ and extend to below the antrum AN. Plication line 402 can terminate above the AN or extend further to the pylorus PY. Figure 9A depicts cross section 9A-9A which shows a dotted line that represents the former location of the stomach GC prior to the region being acquired and plicated. Figure 9A further depicts plication lines 402 and 406, and excluded tissue region 404 that, once plicated, is excluded from communication with the remaining organ volume along the length of the plication.

[0029] Figure 9A illustrates two plication lines 402, 406 created adjacent to one another and creating tissue region 404. Although two plications are shown, a single plication may be created or three or more may be created depending upon the desired effects. Moreover, the plications may be adhered together via fasteners 408 along the length of the plications. Fasteners may include any number of types of fasteners ranging from staples, sutures, clips, helical screws, adhesives, etc. A further detailed discussion on fasteners is described in United States Patent Application Serial Nos. 09/871,297 and 10/188,547, which have been incorporated herein by reference above. Figure 9B shows another view in cross section 9B-9B of the plicated stomach from Figure 9.

[0030] It is anticipated that the placement of partitions or fastening lines, as described above, may vary from those depicted herein as necessary for a physician to achieve a desired clinical effect, or to overcome variations in the anatomy of the patient. These configurations may include, additional plications, various angles along a plication relative to the anatomic location, such as 0° to 180° from the LC, or the GC, depending on the region to be effected. Such configurations that utilize the methods and devices of the present invention are contemplated to be within the scope of this disclosure.

## CLAIMS

We claim:

1. A method of decreasing motility of a stomach, comprising:  
creating at least one plication between a first and a second tissue region from  
within the stomach,

wherein the at least one plication is configured within the stomach such that  
contractions produced by the stomach are attenuated to affect a rate at which contents  
within the stomach are emptied therefrom.

2. The method of claim 1 further comprising creating a plurality of additional  
plications within the stomach.

3. The method of claim 1 wherein creating the at least one plication comprises  
configuring the plication within a fundic region of the stomach.

4. The method of claim 3 further comprising configuring the plication to inhibit  
distension of the stomach within the fundic region.

5. The method of claim 3 further comprising configuring the plication to extend  
between a gastroesophageal junction and a greater curvature of the stomach.

6. The method of claim 1 wherein creating the at least one plication comprises  
configuring the plication within an antrum region of the stomach.

7. The method of claim 6 further comprising configuring the plication to extend at least partially between a fundic region and a distal portion of the stomach.

8. The method of claim 7 further comprising configuring the plication to extend angularly between the fundic region and the distal portion.

9. The method of claim 1 wherein creating the at least one plication comprises configuring the plication to extend at least partially between a lesser curvature and a greater curvature of the stomach.

10. The method of claim 9 further comprising creating a plurality of additional plications within the stomach configured in a radial pattern extending between the lesser curvature and the greater curvature.

11. The method of claim 1 wherein creating the at least one plication comprises configuring the plication to extend from a gastroesophageal junction to a distal portion of the stomach.

12. The method of claim 11 further comprising configuring the at least one plication to extend between a distal end of the at least one plication and a greater curvature of the stomach.

13. A method of inhibiting elongation of a proximal portion of a stomach, comprising:

creating at least one plication between a first and a second tissue region from within the stomach,

wherein the at least one plication extends from adjacent a lower esophageal sphincter to within a lumen of the stomach, and

wherein a placement of the at least one plication is such that a length of the lower esophageal sphincter is maintained during stomach distension.

14. The method of claim 13 wherein creating the at least one plication comprises configuring the plication to extend from a distal portion of the lower esophageal sphincter.

15. The method of claim 13 wherein creating the at least one plication comprises configuring the plication to maintain a consistent length of the lower esophageal sphincter prior to and after stomach distension.

16. The method of claim 13 wherein creating the at least one plication comprises configuring the plication to maintain the length of the lower esophageal sphincter at 2 cm or greater.

17. The method of claim 13 wherein creating the at least one plication comprises configuring the plication parallel to a longitudinal axis defined by the lower esophageal sphincter.

18. The method of claim 13 wherein creating the at least one plication comprises configuring the plication angled relative to a longitudinal axis defined by the lower esophageal sphincter.

19. The method of claim 13 wherein creating the at least one plication comprises configuring the plication to extend along a majority of the stomach.

20. A method of controlling hormone secretion levels within a stomach, comprising:

creating at least one plication between a first and a second tissue region from within the stomach,

wherein the at least one plication is configured such that the hormone secretions from a region of the stomach is impaired by the at least one plication.

21. The method of claim 20 further comprising creating a plurality of additional plications within the stomach.

22. The method of claim 20 wherein creating the plurality of additional plications comprises configuring the plications adjacent to one another along the stomach.

23. The method of claim 20 wherein creating the at least one plication comprises configuring the plication to exclude a fundic region of the stomach from communication with a remaining portion of the stomach.

24. The method of claim 20 wherein creating the at least one plication comprises configuring the plication to extend between a gastro esophageal junction to an antrum of the stomach.

25. The method of claim 24 wherein configuring the plication comprises terminating the plication proximal of the antrum.

26. The method of claim 24 wherein configuring the plication comprises terminating the plication distal of the antrum.

27. The method of claim 20 wherein the hormone comprises Ghrelin.

28. A method of modifying a function of a hollow body organ, said method comprising:

positioning a tissue acquisition device into a gastrointestinal tract of a patient, the gastrointestinal tract having a stomach which comprises an esophagus, a fundus, and an antrum;

acquiring a first tissue region and a second tissue region within a region of the fundus;

fastening the first and second tissue regions together to form a plication such that the plication functions as a barrier to fundic contractions affecting the antrum of the stomach, thereby impacting a rate at which contents of the stomach are emptied into a remaining portion of the gastrointestinal tract.

29. The method of claim 28 further comprising acquiring additional regions of tissue to form additional plications within the region of the fundus.

30. The method of claim 28 wherein the plication is configured to inhibit distension of the stomach within the region of the fundus.

31. The method of claim 28 wherein fastening the first and second tissue regions comprises configuring the plication between a gastroesophageal junction and a greater curvature of the stomach.

32. The method of claim 28 wherein fastening the first and second tissue regions comprises configuring the plication to extend from a gastroesophageal junction to a distal portion of the stomach.

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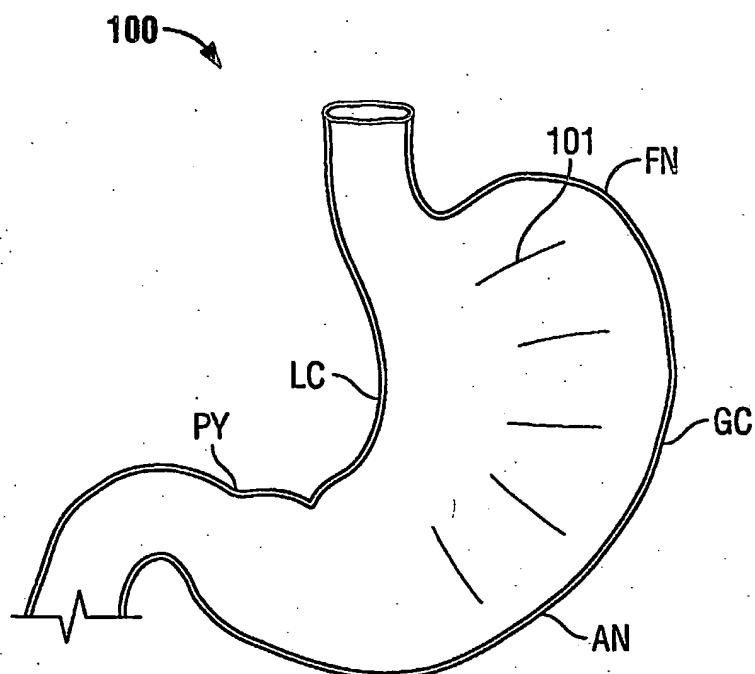


FIG. 5

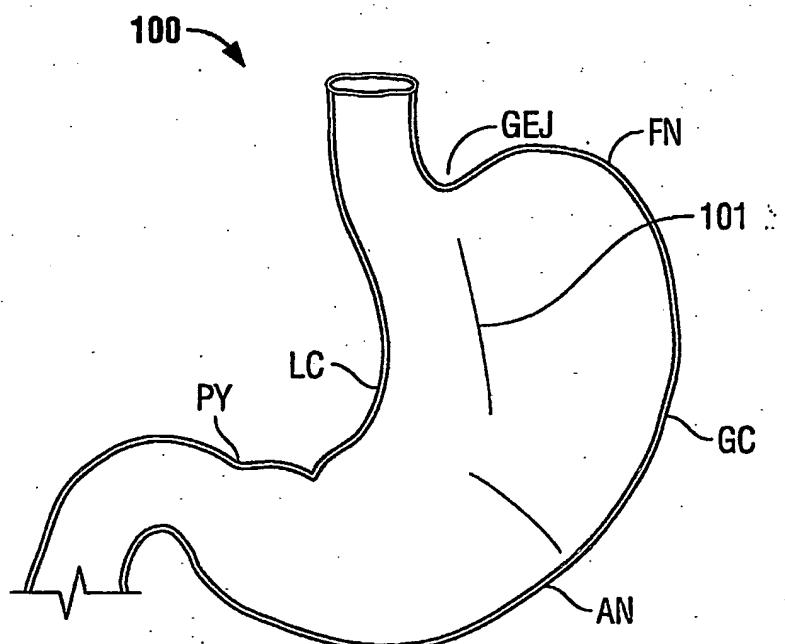


FIG. 6

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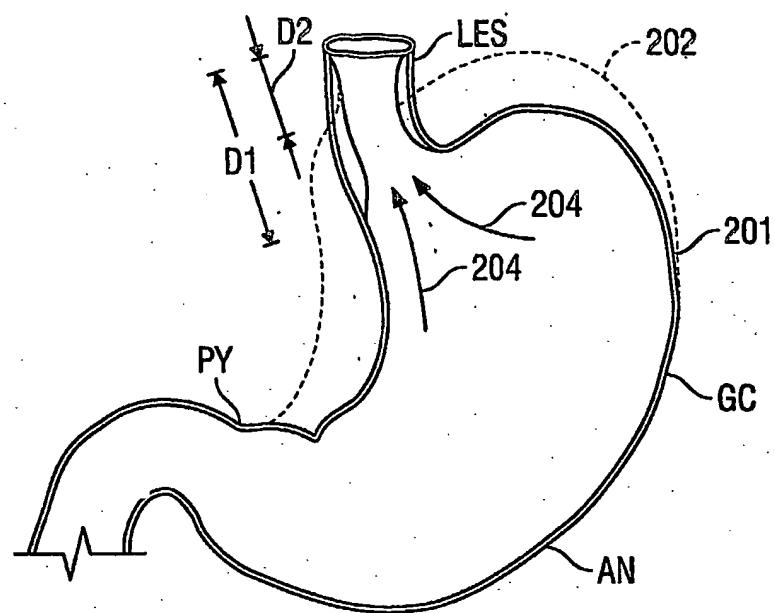


FIG. 7

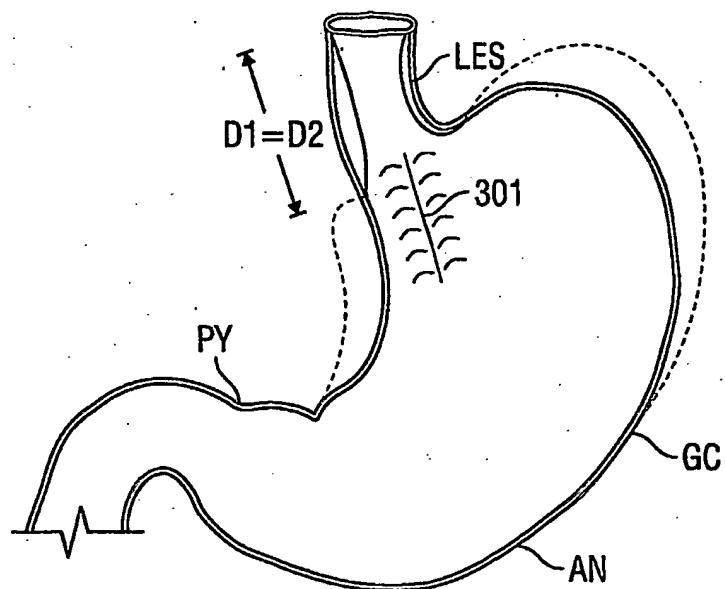


FIG. 8

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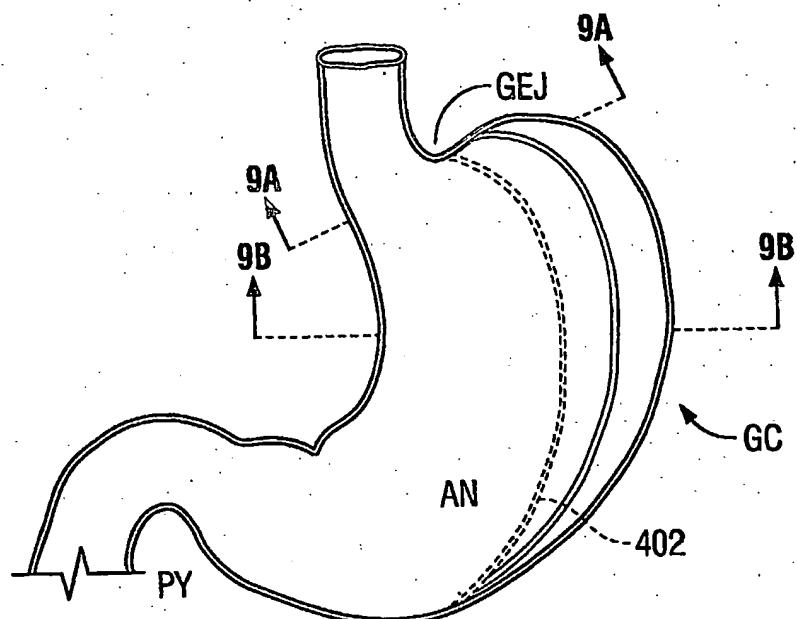


FIG. 9

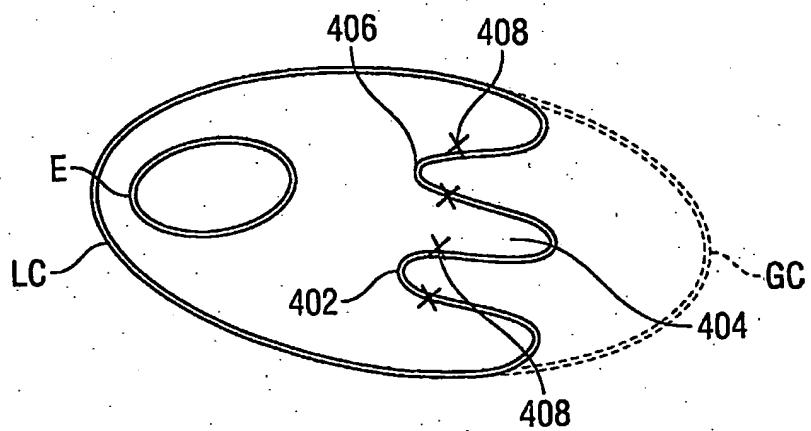


FIG. 9A

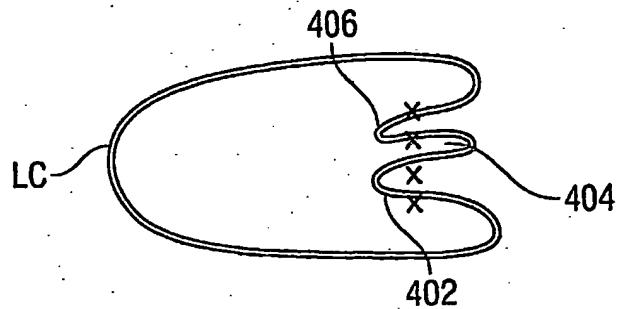


FIG. 9B